

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of:  
James E. Kipp et al.

For: METHOD FOR PREPARING  
SUBMICRON PARTICLE  
SUSPENSIONS

Serial No.: 10/021,692

Filed: December 12, 2001

Examiner: Simon J. Oh

Art Unit: 1615

Conf. No.: 9772

CERTIFICATE OF MAILING

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2<sup>nd</sup> SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington D.C., 20231

Sir:

Pursuant to 37 C.F.R. 1.97, a list of documents is disclosed on the attached form PTO-1449 that may be material to the examination of this application. A copy of each of the documents is enclosed herewith for the Examiner's consideration. No inference should be drawn that the attached list represents a comprehensive investigation of the prior art; that any or all are pertinent to the invention; or that any apparatus disclosed is equivalent to the subject invention.

Applicants do not believe any additional fee is due in connection with this 2<sup>nd</sup> Supplemental Information Disclosure Statement, however, the Commissioner is hereby authorized to change any additional fees (or credit any overpayment) to Deposit Account No. 02-1818.

The identified patents and documents do not suggest or make obvious the claimed invention. Hence, allowance of the pending application is respectfully requested.

Respectfully submitted,  
BELL, BOYD & LLOYD LLC

Date: May 7, 2004

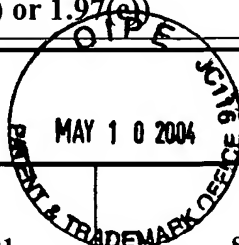
BY

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**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT****(Under 37 CFR 1.97(b) or 1.97(e))**

Docket No.

IFT-5657A

In Re Application Of: **James E. Kipp et al.**

Serial No.

10/021,692

Filing Date

December 12, 2001

Examiner

Simon J. Oh

Group Art Unit

1615

Title: **METHOD FOR PREPARING SUBMICRON PARTICLE SUSPENSIONS**

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Alexandria, VA 22313-1450

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.

IFT-5657A

In Re Application: James E. Kipp et al.

Serial No.

10/021,692

Filing Date

December 12, 2001

Examiner

Simon J. Oh

Group Art Unit

1615

**METHOD FOR PREPARING SUBMICRON PARTICLE SUSPENSIONS****Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

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Dated: May 7, 2004

Robert M. Barrett, Reg. No. 30,142

BELL, BOYD &amp; LLOYD LLC

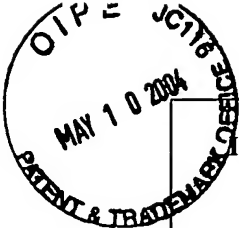
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<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> (use several sheets if necessary)  PTO Form 1449	Atty Docket No. IFT-5657A-2	Application No. 10/021,692
	Applicant Kipp et al.	
	Filing Date Dec. 12, 2001	Group 1615

FOREIGN PATENT DOCUMENTS								
Examiner's Initials		Document Number	Publication Date	Country	Class	Subclass	Translation	
							Yes	No
		EP-0602 702 A1	22 June 1994	EP			X	
		EP 0605 024 A2 EP 0605 024 A3	6 July 1994	EP			X	
		EP 0644 755 B1	19 May 1997	EP			X	
		EP 0720 471 B1	18 Apr 2001	EP			X	
		EP 0730 406 B1	8 July 1998	EP			X	
		EP 0752 245 B1	22 May 2002	EP			X	
		EP 0754 034 B1	22 Jan 1997	EP			X	
		EP 0788 350 B1	27 Feb 2002	EP			X	
		EP 0804 162 B1	5 Sept 2001	EP			X	
		EP 0808 154 B1	20 Dec 2000	EP			X	
		EP 0812 187 B1	2 May 2003	EP			X	
		EP 0820 300 B1	2 Apr. 1996	EP			X	
		EP 0828 479 B1	24 Oct 2001	EP			X	
		EP 0831 770 B1	16 Aug 2000	EP			X	
		EP 0832 569 A2 EP 0832 569 B1	1 Apr 1998 26 Nov 2003	EP			X	
		EP-0988 863 A3	9 Aug 2000	EP			X	
		EP 1012 204 B1	29 Jan 2003	EP			X	
		EP 1105 109 B1	23 Apr 2003	EP			X	
		EP 1156 788 B1	15 Jan 2003	EP			X	
		EP 1210 942 A2	5 June 2002	EP			X	
		WO 85/00011 A1	3 Jan 1985	PCT			X	
		WO 86/03676 A1	3 July 1986	PCT			X	
		WO 89/11850 A1	14 Dec 1989	PCT			X	
		WO 90/03782 A2	19 Apr 1990	PCT			X	
		WO 90/15593 A1	27 Dec 1990	PCT			X	
		WO 91/06292 A1	16 May 1991	PCT			X	
		WO 91/12794 A1	5 Sept 1991	PCT			X	
		WO 91/16068 A1	31 Oct 1991	PCT			X	
		WO 92/00731 A1	23 Jan 1992	PCT			X	
		WO 92/03380 A1	5 Mar 1992	PCT			X	
		WO 93/25190 A1	23 Dec 1993	PCT			X	
		WO 94/20072 A1	15 Sept 1994	PCT			X	
		WO 95/05164 A1	23 Feb 1995	PCT			X	
		WO 95/27482 A1	19 Oct 1995	PCT			X	

Examiner:	Date Considered:
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**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
(use several sheets if necessary)

PTO Form 1449

Atty Docket No. IFT-5657A-2	Application No. 10/021,692
Applicant Kipp et al.	
Filing Date Dec. 12, 2001	Group 1615

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 96/00567 A1	11 Jan 1996	PCT			X	
	WO 96/14833 A1	23 May 1996	PCT			X	
	WO 96/20698 A2	11 July 1996	PCT			X	
	WO 96/24336 A1	15 Aug 1996	PCT			X	
	WO 96/24340 A1	15 Aug 1996	PCT			X	
	WO 96/25150 A1	22 Aug 1996	PCT			X	
	WO 96/25152 A1	22 Aug 1996	PCT			X	
	WO 96/25918 A1	28 Aug 1996	PCT			X	
	WO 96/31231 A1	10 Oct 1996	PCT			X	
	WO 97/03657 A1	19 July 1996	PCT			X	
	WO 97/14407 A1	24 Apr 1997	PCT			X	
	WO 97/30695 A1	28 Aug 1997	PCT			X	
	WO 97/36611 A1	9 Oct 1997	PCT			X	
	WO 97/41837 A2	13 Nov 1997	PCT			X	
	WO 97/44014 A1	27 Nov 1997	PCT			X	
	WO 98/07410 A1	26 Feb 1998	PCT			X	
	WO 98/07414 A1	26 Feb 1998	PCT			X	
	WO 98/14174 A1	9 Apr 1998	PCT			X	
	WO 98/14180 A1	9 Apr 1998	PCT			X	
	WO 98/35666 A1	20 Aug 1998	PCT			X	
	WO 98/57967 A1	23 Dec 1998	PCT			X	
	WO 99/00113 A1	7 Jan 1999	PCT			X	
	WO 99/02665 A1	21 Jan 1999	PCT			X	
	WO 99/03450 A1	29 Jan 1999	PCT			X	
	WO 99/16443 A1	8 Apr 1999	PCT			X	
	WO 99/29316 A1	17 June 1999	PCT			X	
	WO 99/30833 A1	24 June 1999	PCT			X	
	WO 99/32156 A2	1 July 1999	PCT			X	
	WO 99/33467 A1	8 July 1999	PCT			X	
	WO 99/38493 A1	5 Aug 1999	PCT			X	
	WO 99/49846 A2	7 Oct 1999	PCT			X	
	WO 99/49848 A1	7 Oct 1999	PCT			X	
	WO 99/61001 A1	2 Dec 1999	PCT			X	
	WO 99/65469 A3	23 Dec 1999	PCT			X	
	WO 00/09096 B1	24 Feb 2000	PCT			X	

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							Yes	No
		WO 00/12124 A1	9 Mar 2000	PCT			X	
		WO 00/12125 A1	9 Mar 2000	PCT			X	
		WO 00/18374 A1	6 Apr 2000	PCT			X	
		WO 00/27363 A1	18 May 2000	PCT			X	
		WO 00/30615 A1	2 June 2000	PCT			X	
		WO 00/30616 A1	2 June 2000	PCT			X	
		WO 00/37050 A1	29 June 2000	PCT			X	
		WO 00/40220 A1	13 July 2000	PCT			X	
		WO 00/51572 B1	8 Sept 2000	PCT			X	
		WO 00/71079 A2	30 Nov 2000	PCT			X	
		WO 01/12155 A1	22 Feb 2001	PCT			X	
		WO 01/17546 A1	15 Mar 2001	PCT			X	
		WO 01/26635 A2	19 Apr 2001	PCT			X	
		WO 01/62374 A2	30 Aug 2001	PCT			X	
		WO 01/64164 A2	7 Sept 2001	PCT			X	
		WO 01/80828 A2	1 Nov 2001	PCT			X	
		WO 01/85345 A1	15 Nov 2001	PCT			X	
		WO 01/87264 A2	22 Nov 2001	PCT			X	
		WO 02/17883 A2	7 Mar 2002	PCT			X	
		WO 02/24169 A1	28 Mar 2002	PCT			X	
		WO 02/24163 A1	28 Mar 2002	PCT			X	
		WO 02/43702 A2	6 June 2002	PCT			X	
		WO 02/51386 A2	7 July 2002	PCT			X	
		WO 02/55059 A2	18 July 2002	PCT			X	
		WO 02/60411 A2	8 Aug 2002	PCT			X	
		WO 02/72070 A1	19 Sept 2002	PCT			X	
		WO 02/72071 A1	19 Sept 2002	PCT			X	
		WO 02/74282 A1	26 Sept 2002	PCT			X	
		WO 02/80883 A2	17 Oct 2002	PCT			X	
		WO 02/89773 A2	14 Nov 2002	PCT			X	
		WO 03/26611 A2	3 Apr 2003	PCT			X	
		WO 03/26611 A3						
		WO 03/35031 A1	1 May 2003	PCT			X	

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	Applicant Kipp et al.	
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Examiner's Initials	OTHER DOCUMENTS (Including Author Title Date Pertinent Pages Etc.)
	Davis et al., "Pulmonary Perfusion Imaging: Acute Toxicity and Safety Factors as a Function of Particle Size", J.Nucl Med., Vol. 19 (1978), pp. 1209-1213.
	Schroeder et al., "Physiological Effects of Subvisible Microspheres Administered Intravenously to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol. 67, No. 4, April 1978, pp. 508-512.
	Yokel et al., "Acute Toxicity of Latex Microspheres", Toxicity Letters, Vol. 9 (1981), pp. 165-170.
	Allen et al., "Critical Evaluation of Acute Cardiopulmonary Toxicity of Microspheres", J.Nucl Med., Vol. 19 (1987), pp. 1204-1208.
b*	B. Sjostrom et al., "Preparation Of Submicron Drug Particles In Lecithin-Stabilized O/W Emulsions I. Model Studies Of The Precipitation Of Cholesteryl Acetate", Int. J. Pharm., 88 (1992) pp 53-62.
b*	B. Sjostrom et al., "A Method For The Preparation Of Submicron Particles Of Sparingly Water-Soluble Drugs By Precipitation In Oil-In-Water Emulsions. II: Influence Of The Emulsifier, The Solvent And The Drug Substance", J. Pharm. Sci., 82(6), (1992) pp 584-589.
b*	Duncker and Reichelt, "Effects of the Pharmaceutical Cosolvent hydroxypropyl-beta-cyclodextrin on Porcine Corneal Endothelium", Graefe's Archive for Clinical and Experimental Ophthalmology (Germany), 236/5 (1998), pp. 380-389.
b*	Volchek and Dellen, "Anaphylaxis to Intravenous Cyclosporine and Tolerance to Oral Cyclosporine, Case Report and Review", Annals of Allergy, Asthma, and Immunology, 80 (1998), pp. 159-163.
b*	Singla et al., "Paclitaxel and its Formulations", International Journal of Pharmaceutics, 235/1-2 (2002), pp. 179-192.
	B. Sjostrom et al., "The Formation of Submicron Organic Particles by Precipitation in an Emulsion", J.Dispersion Science and Technology, 15(1), 89-117 (1994).
re*	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Synthetic Products - Functionalized Phospholipids: Lipids for Conjugation of Proteins/Peptides/Drugs to Liposomes" (7 pgs), March 2003.
	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Functionalized PEG Lipids" (3 pgs), March 2003.
	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Poly(ethylene glycol)-Lipid Conjugates" (8 pgs) , March 2003.

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a\* I received only 5 pages  
 b\* I did not receive those documents